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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/423,037

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DAVID MICHAEL HEERY

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ROPES & GRAY LLP

PATENT DOCKETING 39/41

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EXAMINER

DUNSTON, JENNIFER ANN

ART UNIT

PAPER NUMBER

1636

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

09/423,037

**Applicant(s)**

HEERY ET AL.

**Examiner**

Jennifer Dunston

**Art Unit**

1636

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 December 2008 and 15 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 3-22 is/are pending in the application.
- 4a) Of the above claim(s) 5, 6 and 14-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 4 and 7-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 October 1999 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/10/2008 has been entered.

Receipt is acknowledged of an amendment, filed 12/10/2008, in which claim 1 was amended. Receipt is also acknowledged of an amendment, filed 4/15/2009, in which claim 1 was amended. Claims 1 and 3-22 are pending.

### *Election/Restrictions*

Applicant elected Group I, LXXLL, SRC-1 and oestrogen receptor species without traverse in the reply filed 11/13/2001.

Claims 14-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/13/2001.

Claims 5-6 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/13/2001.

Currently, claims 1, 3, 4 and 7-13 are under consideration.

*Specification*

The amendment filed 4/15/2009 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the sequence XLXXLLLXXX (SEQ ID NO: 82), which was added to the sequence listing in the amendment filed 4/15/2009. This sequence was not present in the originally filed disclosure.

The response filed 12/10/2008 notes that the sequence was not explicitly recited in the instant specification; however, the response asserts that the sequence is described inherently at page 1, lines 24-25, where the specification makes direct reference to the NR box described in Figure 3D of Le Douarin. The response asserts that this figure clearly delineates a 10-amino acid region as being the "NR box", and the common pattern of conserved leucine residues is indicated by boxes around the L's representing those residues. Accordingly, the response asserts that one of skill in the art would immediately recognize that the "NR box" indicated by the reference in the specification is the sequence XLXXLLLXXX. Furthermore, the response refers to page 8 of the specification, which indicates that the NR box of Le Douarin does not disclose the subject signature motif in that there is no disclosure that the X residues at the beginning and end of the NR box may be omitted, and there is not indication that the fourth L residue is not required, and points out that only four sequences disclosed in Figure 3A and 4 have an NR box. The response asserts that the specific reference to the NR box of Figure 3D of Le Douarin, the manner in which this sequence operatively describes exactly four of the sequences in Figures 3A and 4 as indicated in the instant specification, it would have been clear to the skilled artisan that

no other sequence could have been intended, and that the NR box described in the specification is essentially synonymous with the sequence XLXXLLXXX. Thus, the response asserts that replacing the term "NR box" with the specific sequence that one of skill in the art would understand was meant by that term does not introduce new matter. Moreover, the response assert that because Applicants conceived of a set of sequences that have a signature sequence B<sup>1</sup>XXLL but do not have an NR box as disclosed by Le Douarin, it is clear that Applicant was in possession of the set of sequences comprising a signature sequence B<sup>1</sup>XXLL but lacking an NR box.

The as-filed specification does not provide literal or inherent support for the genus of sequences described by the formula XLXXLLXXX. The specification refers to the sequences of Figure 3D of Le Douarin et al, which are reproduced in Figure 3A of the originally filed specification. These sequences are the following: VLKQLLSENC, ILTSLLNSSQ, and TLRSLNPHL. These three species are not sufficient to support the 64 million sequences encompassed by the formula XLXXLLXXX.

Applicant is required to cancel the new matter in the reply to this Office Action.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 4 and 7-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which

was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

In the reply filed 12/10/2008, independent claim 1 was amended to replace the phrase "provided that the fragment does not comprise a 'NR box' sequence" with the phrase "provided that the fragment does not comprise a sequence XLXXLLLXXX. The amendment to claim 1 filed 4/15/2009, provided a sequence identifier for the XLXXLLLXXX sequence, which was not previously present in the sequence listing.

The response filed 12/10/2008 notes that the sequence was not explicitly recited in the instant specification; however, the response asserts that the sequence is described inherently at page 1, lines 24-25, where the specification makes direct reference to the NR box described in Figure 3D of Le Douarin. The response asserts that this figure clearly delineates a 10-amino acid region as being the "NR box", and the common pattern of conserved leucine residues is indicated by boxes around the L's representing those residues. Accordingly, the response asserts that one of skill in the art would immediately recognize that the "NR box" indicated by the reference in the specification is the sequence XLXXLLLXXX. Furthermore, the response refers to page 8 of the specification, which indicates that the NR box of Le Douarin does not disclose the subject signature motif in that there is no disclosure that the X residues at the beginning and end of the NR box may be omitted, and there is no indication that the fourth L residue is not required, and points out that only four sequences disclosed in Figure 3A and 4 have an NR box. The response asserts that the specific reference to the NR box of Figure 3D of Le Douarin, the manner in which this sequence operatively describes exactly four of the sequences in Figures 3A

and 4 as indicated in the instant specification, it would have been clear to the skilled artisan that no other sequence could have been intended, and that the NR box described in the specification is essentially synonymous with the sequence XLXXLLXXX. Thus, the response asserts that replacing the term "NR box" with the specific sequence that one of skill in the art would understand was meant by that term does not introduce new matter. Moreover, the response assert that because Applicants conceived of a set of sequences that have a signature sequence B<sup>1</sup>XXLL but do not have an NR box as disclosed by Le Douarin, it is clear that Applicant was in possession of the set of sequences comprising a signature sequence B<sup>1</sup>XXLL but lacking an NR box.

Any negative limitation or exclusionary proviso must have basis in the original disclosure. If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. The as-filed specification does not provide literal or inherent support for the genus of sequences described by the formula XLXXLLXXX. The specification refers to the sequences of Figure 3D of Le Douarin et al, which are reproduced in Figure 3A of the originally filed specification. These sequences are the following: VLKQLLLSENC, ILTSLLNSSQ, and TLRSLNPHL. These three species are not sufficient to support the 64 million sequences encompassed by the formula XLXXLLXXX. Thus, the specification does not provide support for presence of or the exclusion of the sequences of the formula XLXXLLXXX. Furthermore, the specification teaches that LXXLL motif is found in TIF1, TIF2, p300, RIP 140 and the TRIP proteins, and discloses that RIP140, TIF1, and Trip3 are preferred nuclear coactivator proteins of the present invention (e.g., page 4, lines 7-18). TIF1 and Trip3 proteins contain only one LXXLL motif, which falls within the generic sequence of

XLXXLLLXXX (e.g., Figure 3A). Clearly, the specification does not provide support for the use of these proteins without the XLXXLLLXXX motif.

The original specification, drawings and claims were thoroughly reviewed and no support could be found for the amendment. Accordingly, the amendment is a departure from the specification and claims as originally filed, and the passages that Applicant has provided do not provide support.

***Response to Arguments - 35 USC § 112***

The previous rejection of claims 1, 3, 4 and 7-13 under 35 U.S.C. 112, first paragraph (written description), has been withdrawn in view of Applicant's amendment to the claims in the reply filed 12/10/2008.

The previous rejection of claims 1, 3, 4 and 7-13 under 35 U.S.C. 112, first paragraph (enablement), has been withdrawn in view of Applicant's amendment to the claims in the reply filed 12/10/2008.

***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dunston whose telephone number is (571)272-2916. The examiner can normally be reached on M-F, 9 am to 5 pm.



If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jennifer Dunston/  
Examiner  
Art Unit 1636